

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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IN RE: NEW ENGLAND	)	
COMPOUNDING PHARMACY, INC.	)	1:13-md-02419-FDS
PRODUCTS LIABILITY LITIGATION	)	
	)	
This Document Relates To:	)	
	)	
JOAN HULSEY AND GUY HULSEY	)	
	)	
Plaintiffs.	)	
	)	
v.	)	1:13-cv-12961-FDS
	)	
MARION PAIN MANAGEMENT	)	
CENTER, INC., MANGALA J.	)	
SHETTY, MD,	)	
	)	
Defendants.	)	
	)	
	)	

**DEFENDANTS, MARION PAIN MANAGEMENT CENTER, INC. AND  
MANGALA J. SHETTY, M.D.'S  
MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS  
PLAINTIFFS' SHORT FORM COMPLAINT**

## I. BACKGROUND

The Plaintiffs filed their SFC as part of the multidistrict litigation pending in the United States District Court for the District of Massachusetts (“MDL”). As the Court is aware, the MDL relates to an outbreak of fungal meningitis and other infections that were caused by the presence of fungus in tainted lots of methylprednisolone acetate (“MPA”) that were manufactured, sold and distributed by the New England Compounding Center (“NECC”). There is little doubt that the conduct of NECC and the Affiliated Defendants (entities responsible for, among other things, the design and construction of NECC’s

“clean rooms” and the cleaning and maintenance of the “clean rooms”) caused certain lots of MPA to be tainted with fungus. The specific lots of MPA that were ultimately found to be tainted with fungus included, but were not limited to, Lot# 06292012@26 and Lot #0512012@68. The Defendants, Marion Pain Management Center, Inc. (“Marion”) and Mangala J. Shetty, M.D., obtained MPA from the above referenced lots from NECC. Along with the lots, the Defendants were provided Microbiology Reports provided by Analytical Research Laboratories (“ARL”) on behalf of its “client” NECC. The Microbiology Reports certified to the Defendants that these lots had been tested and that their contents were “sterile.” A true and correct copy of the Microbiology Reports are attached hereto as Exhibit “A.”

The Plaintiffs allege that the decedent, Guy Hulsey, Jr. received an injection of MPA on September 4, 2012 administered by Dr. Shetty at Marion. *See*, Corrected Short Form Complaint Against Unaffiliated Defendants (“SFC”) at Paragraph 5-6. A true and correct copy of the SFC is attached hereto as Exhibit “B.” As a result of the administration of MPA, the Plaintiffs allege that Guy Hulsey, Jr. suffered “bodily injury; pain and suffering, and death.” *See*, SFC Paragraph at 8. Plaintiff, Joan Hulsey alleges that as a result of the death of Guy Hulsey, Jr., she suffered loss of consortium. *See*, SFC at Paragraph 9.

The Plaintiffs SFC incorporates by reference various allegations and claims as set forth in the Master Complaint (“MC”) (Dkt. No. 545) that was filed in this MDL on or around November 5, 2013. Specifically, the Plaintiffs assert the following claims that are applicable against the Moving Defendants:<sup>1</sup>

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<sup>1</sup> The SFC also incorporates two claims (Count II and Count VI) which are directed against UniFirst Corporation (“UniFirst”) only and one claim (Count IX) that is directed against the Tennessee Clinic

- Count III – Negligence and Gross Negligence (Against Clinic Related Defendants)
- Count IV – Violation of State Consumer Protection Statutes (Against Clinic Related Defendants)
- Count VII – Battery (Against Clinic Related Defendants)
- Count VIII – Failure to Warn (Against Clinic Related Defendants)
- Count X – Agency (Against Clinic Related Defendants)
- Count XI – Civil Conspiracy (Against Clinic Related Defendants)
- Count XII – Wrongful Death (Against Each Defendant)
- Count XIII – Loss of Consortium (Against All Defendants)
- Count XIV – Punitive Damages (Against All Defendants)

For the reasons set forth in the Defendants’ Motion to Dismiss and as articulated further below, the Defendants allege that the Plaintiffs’ claims fail to state claims upon which relief can be granted. Specifically, the Defendants assert that the SFC is deficient in the following respects:

- The Plaintiffs have failed to comply with the Florida Malpractice Act and its pre-suit requirements;
- The Plaintiffs have failed to allege that the Defendants breached any duty owed to the Plaintiffs sufficient to support their claims in Count III – Negligence and Gross Negligence;
- The Plaintiffs’ claims in Count IV asserting violations of the Florida Consumer Protection Statute, must fail as that statute specifically does not apply to claims for personal injuries;
- The Plaintiffs’ claims for Battery in Count VII must fail as Guy Hulsey, Jr. specifically consented to the procedure which forms the basis of the Plaintiffs’ claims;
- The Plaintiffs’ claims for Failure to Warn in Count VIII must fail as Plaintiffs admit Defendants warned Mr. Hulsey of the risks involved with the MPA injections;

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Related Defendants only. Because these claims are not directed against the Moving Defendants, they are not addressed in this Motion. However, the failure to substantively address these claims shall not constitute a waiver to do so in the future should the Plaintiffs attempt to assert these claims against the Moving Defendants.

- The Plaintiffs' claims of Agency in Count X must fail as they cannot establish that there was an agency relationship between the Defendants and NECC;
- The Plaintiffs claims do not meet the requirements of Civil Conspiracy under Florida law and therefore, Count XI must be dismissed;
- The Plaintiffs' claims of Wrongful Death in Count XII must be dismissed because the Plaintiffs have failed to comply with the Florida Malpractice Act and its pre-suit requirements;
- The Plaintiffs' claims of Loss of Consortium in Count XIII must be dismissed because all actionable torts against Defendants will likely be dismissed and a Loss of Consortium claim is dependent upon the existence of an actionable tort;
- The Plaintiffs' claims are insufficient to support a claim for Punitive Damages under Florida law and therefore, Count XIV must be dismissed.

The Defendants, Marion and Dr. Shetty, are not responsible for any harm that the Plaintiffs allegedly suffered as a result of receiving MPA. Marion and Dr. Shetty bear no responsibility for NECC's conduct, sterility practices, procedures or other methods which allegedly resulted in the production, distribution and supply of certain lots of MPA which may have contained fungal contamination. The Plaintiffs have failed to assert any cause of action that could impose liability on Marion and Dr. Shetty despite their best efforts to impose upon the Defendants liability for the conduct of NECC and the other Affiliated Defendants, where responsibility ultimately lies.

## **II. STANDARD OF REVIEW**

To overcome a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the factual allegations in a complaint must "possess enough heft" to set forth "a plausible entitlement to relief." *Thomas v. Rhode Island*, 542 F.3d 944, 948 (1st Cir. 2008) *quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 546, 127 S. Ct. 1955, 1959, 167 L. Ed. 2d 929 (2007). Dismissal is appropriate when the complaint fails to plead sufficient facts demonstrating

a plausible entitlement to the relief requested. *Twombly*, 127 S. Ct. at 1964-65. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009). Bare allegations, labels, legal conclusions and/or a "formulaic recitation of a cause of action's elements will not do." *Twombly*, 127 S. Ct. at 1964-65.

In the present case, as will be demonstrated in more detail below, the Plaintiffs' SFC and the portions of the MC that are incorporated therein are replete with bare allegations, legal conclusions and formulaic recitations. This should come as no surprise given the posture of this case. NECC is essentially bankrupt and the Plaintiffs fear that the resources of the other Affiliated Defendants will not be sufficient to remedy the harm caused by these defendants' conduct. Consequently, the Plaintiffs are desperate to affix blame to Unaffiliated Clinic Defendants such as Marion and its physician, Dr. Shetty in the hopes of finding more pockets to satisfy their recovery. However, this explanation does not justify relaxing the applicable pleading standards. As outlined below, the Plaintiffs' allegations fail to contain sufficient factual matter, which, if accepted as true, express a "plausible entitlement to relief" on their face. *Iqbal*, 556 U.S. at 681. (Stating that "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citations omitted)). The allegations set forth in the SFC and the MC fail to state plausible claims that can survive this Motion to Dismiss.

### III. ARGUMENT

#### A. Plaintiffs' Claims Under Count III, Negligence and Gross Negligence (Against Clinic Related Defendants), Must be Dismissed Because Plaintiffs Failed to Comply With Florida's Medical Malpractice Statutory Pre-Suit Requirements

Plaintiffs' Count III, Negligence and Gross Negligence against Defendants, must be dismissed because Plaintiffs failed to comply with Florida's Medical Malpractice Statutory Pre-Suit Requirements. A plaintiff in federal court must comply with the Florida Medical Malpractice Act (hereinafter the "Act") in order to maintain an action against a healthcare provider. *Gullo v. Prison Health Servs., Inc.*, 2007 WL 3340396 (M.D. Fla. Nov. 9, 2007) (dismissing Complaint because the resolution of the case would require the application of the prevailing professional standard of care for a healthcare provider, and therefore, the Court determined that plaintiff was required to comply with the presuit procedural statutory requirements); *Weinstock v. Groth*, 629 So. 2d 835 (Fla. 1993). A healthcare provider is defined by Florida Statute 766.202(4), to include any hospital, ambulatory surgical center, or [...] any person licensed under chapter 458 [...].

The Act incorporates a pre-suit investigation procedure under which the claimant and defendants must comply before a medical malpractice suit may be filed in court. *Fla. Stat.* § 766.106. In order to determine whether the pre-suit requirement of chapter 766 applies, the question is whether the plaintiff must rely upon the medical negligence standard of care, as set forth in section 766.102(1), Florida Statutes (2005), in order to succeed in the plaintiff's case. *Integrated Health Care Servs., Inc. v. Lang-Redway*, 840 So. 2d 974, 980 (Fla. 2002). A negligence claim is subject to the medical malpractice presuit screening requirements if the wrongful act is directly related to the improper

application of medical services and use of professional judgment or skill. *Id.* at 369 (citing *Lynn v. Mount Sinai Med. Ctr., Inc.*, 692 So. 2d 1002, 1003 (Fla. 3<sup>rd</sup> DCA 1997)).

A critical component of the Act requires the claimant to “notify each prospective defendant...of intent to initiate litigation for medical negligence.” *Fla. Stat.* § 766.106(2); *Moss v. Stadlan, M.D.*, 789 So. 2d 1069 (Fla. 4th DCA 2001); *Goldfarb v. Urcuoli*, 858 So. 2d 397 (Fla. 1st DCA 2003). Prospective defendants that are entitled to pre-suit notice under the foregoing section are “health care providers” listed in *Fla. Stat.* § 766.102(1), which include pain management clinics as defined in *Fla. Stat.* § 458.2265.

The Act states “[n]otice to each prospective defendant must include, if available, a list of all known health care providers seen by the claimant for the injuries complained of subsequent to the alleged act of negligence, all known health care providers during the 2-year period prior to the alleged act of negligence who treated or evaluated the claimant, and copies of all of the medical records relied upon by the expert in signing the affidavit” discussed in the following paragraphs. *Fla. Stat.* §766.106(2)(a).

The Act requires claimants to conduct an investigation prior to initiating a lawsuit or filing a notice of intent. *See Fla. Stat.* § 766.203(2). (“Corroboration of reasonable grounds to initiate medical negligence litigation shall be provided by the claimant’s submission of a verified written medical expert opinion from a medical expert...at the time the notice of intent to initiate litigation is mailed.”). The purpose of requiring a medical malpractice claimant to provide a corroborating medical opinion is to assure the legitimacy of the claim and to prevent the filing of baseless claims. *Yocom v. Wuesthoff Health Systems, Inc.*, 880 So. 2d 787 (Fla. 5<sup>th</sup> DCA 2004). Failure to provide the required medical expert opinion at the time of sending a notice of intent is grounds for

dismissal. *Id.* (emphasis added); *see also Godbold v. Cox-Novoa*, 730 So. 2d 767 (Fla. 5<sup>th</sup> DCA 1999) (appellate court held the trial court should have dismissed plaintiff's claims for failure to provide a supporting expert affidavit with the notice of intent); *and Cohen v. West Boca Medical Center, Inc.*, 854 So. 2d 276 (Fla. 4<sup>th</sup> DCA 2003) (trial court appropriately dismissed plaintiff's claim for failing to comply with presuit requirements pertaining to an unqualified supporting affidavit).

In *Yocom*, the plaintiff sent defendant Wuesthoff a Notice of Intent but failed to include a supporting affidavit. *See Yocom*, 880 So. 2d at 788. The appellate court affirmed the dismissal of Yocom's complaint. *Id.* In *Otto v. Rodriguez*, 710 So. 2d 1 (Fla. 4<sup>th</sup> DCA 1998), the plaintiff filed a lawsuit without providing the appropriate notice of intent and corroborating affidavit because plaintiff did not receive a complete set of medical records from the defendant healthcare provider. *See Otto v. Rodriguez*, 710 So. 2d at 2. The court found that the failure to provide the medical records waived the plaintiff's requirement to provide a corroborating affidavit; however, not a waiver of the notice of intent. *Id.*

In the case at bar, Plaintiffs' negligence and gross negligence claims undeniably arise under a theory of medical malpractice because the complained of actions occurred at a pain management clinic, Marion Pain Management Center, and arise from Dr. Shetty performing a medical procedure on Mr. Hulsey. Dr. Shetty injected the subject MPA (a medical steroid) into Mr. Hulsey. As such the Act requires Plaintiffs to comply with the pre-suit investigation procedure, including the submission of an affidavit by a medical expert, before a medical malpractice suit may be filed in court. *See Fla. Stat.* § 766.106. Plaintiffs' failure to file a Notice of Intent to Initiate Litigation against Defendants along



with a corresponding expert Affidavit is fatal to their claim and the instant count must be dismissed.

**B. Plaintiffs' Claims Under Count IV, the Florida Deceptive and Unfair Trade Practices Act, Must be Dismissed Because Claims for Personal Injury or Death are Specifically Excluded by the Statute**

The Plaintiffs' SFC incorporates by reference the claims set forth in Count VI of the MC asserting violations of state consumer protection statutes. Specifically, the MC references *Fla. Stat.* §§ 501.201 et. seq. *See*, Paragraph 264 of the MC. This statute is known as the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"). Additionally, the SFC references § 501.204 of the FDUTPA. *See*, Paragraph 7. The FDUTPA specifies that it **does not** apply to a "claim for personal injury or death." *Fla. Stat.* § 501.212. The FDUTPA's preclusion of claims for personal injury or death specifically bars the Plaintiffs' claims under Count VI and should, therefore be dismissed. *T.W.M. and S.M. v. American Medical Systems, Inc.*, 886 F.Supp. 842, 844 (N.D. Florida 1995) (granting a Motion to Dismiss claims for personal injuries or death, including claims for loss of consortium, asserted against a manufacturer of a penile implant).

Undeniably, Plaintiffs are seeking to recover for the personal injuries and death of Guy Hulsey, Jr. Plaintiffs allege that Mr. Hulsey suffered "bodily injury; pain and suffering, and death as a result of contracting fungal meningitis" as a result of the administration of MPA manufactured and distributed by NECC. *See* Paragraph 8 of the SFC. To the extent not otherwise addressed below, the claims for loss of consortium that have been asserted by Joan Hulsey (*See* Paragraph 9 of the SFC), must also be dismissed as such claims cannot be premised upon a claims under the FDUTPA. *T.W.M. and S.M.*, 886 F.Supp. at 844.

**C. Plaintiffs' Claims Under Count VII, for Battery, Must Be Dismissed as Guy Hulsey, Jr. Specifically Consented to the Procedure and Because the Plaintiffs Have Failed to Plead that the Consent Obtained Deviated From the Applicable Standard of Care**

The Plaintiffs SFC incorporates Count VII – Battery of the MC. That Count contends that the Plaintiffs “were unaware of the substantial health and safety risk inherent in the use of NECC Contaminated Drugs and did not consent to the injection of contaminated drugs into their bodies.” *See* Paragraph 297 of the MC. The Plaintiffs assert that as a result of this “unwarranted harmful contact” they suffered harm. *See* Paragraph 298 of the MC.

In Florida, there are two bases for asserting a claim for battery in the context of providing medical care and treatment. The first type of case involves a situation where there is a complete lack of consent for the medical procedure performed. *See Zaretsky v. Jacobson*, 99 So.2d 730, 731 (Fla. 3d DCA 1958) (implicitly holding that in a case where the patient alleges that he did not consent to the procedure performed, expert testimony is not required). The second type of case, often described as involving the doctrine of informed consent, involves a situation where it is alleged that the medical provider failed to provide “a proper medical disclosure” regarding the procedure to be performed. *See Gouveia v. Phillips*, 823 So.2d 215, 225 (Fla. 4<sup>th</sup> DCA 2002) (citations omitted) (holding that a case asserting a failure to obtain informed consent requires expert testimony “as to the standard of disclosure within the relevant medical community.”), *See also Meretsky v. Ellenby*, 370 So.2d 1222, 1223 (Fla. 3d DCA 1979) (distinguishing between a claim for a failure to obtain any consent from a failure to make a medically proper disclosure to validate a consent that was actually provided). When considered in a light most favorable

to the Plaintiffs, the allegations set forth in the SFC and the MC fail to state a claim for relief under either theory of liability.

Clearly, this is not a case where Marion and/or Dr. Shetty performed a steroid injection without first obtaining the patient's consent. To the contrary, Guy Hulsey, Jr. signed a detailed Consent to Perform Pain Management Procedures, a true and correct copy of which is attached hereto as Exhibit "C." The Consent form signed by Mr. Hulsey clearly indicated the risks of the procedure as including, among other things, "infection, meningitis, . . . increased pain or even death." Therefore, this is not a case, such as *Zaretsky*, where there was a lack of consent and therefore, the Plaintiffs' claims, if presumed to be asserted under this theory, must be dismissed.

The Plaintiffs have likewise failed to state a claim for relief under an informed consent theory because such a contention would require compliance with Florida's Medical Malpractice Statutory Pre-Suit Requirements including "the claimant's submission of a verified written medical expert opinion from a medical expert" that the consent obtained by Mr. Hulsey did not meet "the standard of disclosure within the relevant medical community" as required under Florida law. *Gouveia v. Phillips*, 823 So.2d 215, 225 (Fla. 4<sup>th</sup> DCA 2002) and *Fla. Stat.* § 766.203(2). Not only has no such affidavit from a medical expert been provided to satisfy Florida's Medical Malpractice Statutory Pre-Suit Requirements, but the allegations asserted in the SFC and MC are utterly devoid of any contention that the consent obtained by Marion and Dr. Shetty deviated from the applicable standard in their medical community for this type of procedure.

The sole basis for the Plaintiffs' Battery claim is the unsubstantiated assertion that Marion and/or Dr. Shetty somehow knew that the MPA used in Mr. Hulsey's procedure was "not sterile." *See* Plaintiffs' MC at Paragraph 297. Missing from the MC is the fact that neither Marion nor Dr. Shetty was aware that the NECC medication that they purchased was contaminated. Even if we accept, for the purpose of this Motion, that the medication was in fact contaminated, the Plaintiffs' arguments must fail as they assume, without providing any factual basis to support their assumption, that Marion and Dr. Shetty were aware that the medication was contaminated. To the contrary, as set forth in the Microbiology Reports attached hereto as Exhibit "A," Marion and Dr. Shetty were provided certifications by ARL, on behalf of NECC, that the MPA was sterile. Taken as a whole, and viewed in a light most favorable to the Plaintiffs, their Battery claim must fail for the reasons set forth above: (1) Mr. Hulsey signed a valid Consent, and (2) the Plaintiffs have failed to even allege that the Consent was not a proper medical disclosure for this community.

Moreover, the Plaintiffs' Battery claim must fail as a matter of law because under the Florida Medical Consent Law, Fla. Stat. § 766.103, the Consent signed by Mr. Hulsey precludes any claim for battery. The Florida Medical Consent Law, prohibits recovery for any claim alleging a lack of informed consent when the physician obtains the consent of the patient "in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community" and where a "reasonable individual . . . would have a general understanding of the procedure." *Fla. Stat. § 766.103(3)(a)(1-2)*. Where the conditions set forth in § 766.103(3) are "evidenced in writing. . . a rebuttable presumption

of a valid consent” is raised. *Fla. Stat.* § 766.103(4)(a). Therefore, the Plaintiffs’ Battery claim fails as a matter of law.

**D. Plaintiffs’ Claims Under Count VIII, Failure to Warn (Against Clinic Related Defendants), Must be Dismissed Because Plaintiffs Admit that Defendants Warned Mr. Hulsey of the Risks Involved**

The Plaintiffs claim that Defendants provided “high risk and unreasonably dangerous NECC Contaminated Drug to patients, including [Mr. Hulsey], in the place of safe, medically acceptable drugs,” and failed to warn of the dangers of the subject medications. *See* Paragraphs 300 and 301 of the MC. Plaintiffs admit that Defendants provided a consent form, which they read and agreed to move forward with the injection. *See* Paragraphs 302 of the MC. *See* Exhibit C. Plaintiffs, however, allege that either the consent form or Defendants should have warned the Plaintiffs “of the inferior and unreasonably dangerous nature of the NECC drug that would be administered to Plaintiffs.” *See* MC at Paragraphs 302.

The Florida Supreme Court held that “[w]hile in many instances the adequacy of warnings concerning drugs is a question of fact, we hold that it can become a question of law where the warning is accurate, clear, and unambiguous.” *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 105 (Fla. 1989).

Defendants provided Mr. Hulsey with a “Consent to Perform Pain Management Procedures,” as well as “Procedure Instructions” and “Discharge Instructions” every time a procedure, including injecting NECC medication, was administered. The Consent identified possible complications, including “infection, meningitis, . . . increased pain or even death.” The warning was “accurate, clear, and unambiguous.” *See* Exhibit B. Accordingly, based upon *Felix*, Defendants satisfied the duty to warn. Also, Plaintiffs’

allegations within the MC and SFC support that the Defendants provided warning to Mr. Hulsey and the instant count must be dismissed.

Plaintiffs attempt to take the duty to warn one huge step higher without any authority or supporting affidavit to support their position. As stated *supra*, Plaintiffs admit that Defendants warned Mr. Hulsey of the possible complications and risks associated with receiving MPA injections; however, Plaintiffs claim Defendants should also have anticipated that third party entities outside their control would have acted negligently, causing the subject NECC medications to become contaminated.

While the count must be dismissed as discussed *supra*, Plaintiffs' Count must still be dismissed for two additional reasons. First, missing from the MC is the fact that neither Marion nor Dr. Shetty was aware that the NECC medication that they purchased was contaminated. Even if we accept, for the purpose of this Motion, that the medication was in fact contaminated, the Plaintiffs' arguments must fail as they assume that Marion and Dr. Shetty were aware that the medication was contaminated. Plaintiffs have presented no evidence to support this assumption, and the evidence suggests a contrary conclusion. As set forth in the Microbiology Reports attached hereto as Exhibit "A," Marion and Dr. Shetty were provided certifications by ARL, on behalf of NECC, that the medication they received was sterile.

Second, the MPA, if properly compounded, is not "inferior" or "unreasonably dangerous" as alleged by the Plaintiffs. Within the instant MC and SFC, Plaintiffs claim that Liberty and UniFirst's negligence caused or contributed to the contamination of the subject MPA lots that are central to Plaintiffs' injuries. *See* Count I and II of the MC. But for Liberty's and UniFirst's, as well as NECC's, actions and inactions, the MPA would

not have been contaminated. These entities actions were outside the control of Defendants and Defendants were unaware at the time of administering the drugs that these entities acted negligently. Accordingly, Defendants administered what they believed to be properly compounded MPA. Defendants' duties to warn were satisfied by the Consent forms discussed above, and Plaintiffs fail to cite authority to support that Defendants had a duty to warn above and beyond the previously given warning. Accordingly, the instant count must be dismissed.

In the alternative, Plaintiffs' allegations of failure to warn stem from an allegation of medical malpractice, and because Plaintiffs failed to comply with Florida's Medical Malpractice Statutory Pre-Suit Requirements, the count must be dismissed.

Under section 766.106(1)(a), Florida Statutes, "claim for medical malpractice" is defined as "a claim arising out of the rendering of, or the failure to render, medical care or services." *Broadway v. Bay Hosp., Inc.*, 638 So. 2d 176, 177 (Fla. 1st DCA 1994). A person seeking recovery for injury resulting from medical malpractice must prove that the injury resulted from a breach of the prevailing professional standard of care as set forth in Section 766.102(1) of the, Florida Statutes. *Id.* The test for determining whether a defendant is entitled to the benefit of the presuit screening requirements of section 766.106, Florida Statutes, is whether the defendant is directly or vicariously liable under the medical negligence standard of care set forth in section 766.102(1), Florida Statutes. *Id.* (citing *Weinstock v. Groth*, 629 So.2d 835 (Fla.1993)).

From the face of the complaint, it is apparent that Plaintiffs have sued Defendants for "performing medical services" (i.e. injecting subject MPA and warning of the risks

associated with same). The complaint on its face alleges breach of a professional standard of care and the instant count must be dismissed.

**E. Plaintiffs' Claims Under Count X, Agency (Against Clinic Related Defendants), Must be Dismissed Because Plaintiffs Cannot Establish There Was An Agency Relationship Between the Defendants and NECC**

The Plaintiffs seek to establish a fiduciary relationship between NECC and Defendants based upon the absurd reasoning that Defendants contracted with NECC to procure compounded drugs from NECC for their patients. Specifically, that NECC was acting as an agent of the Defendants, and Defendants “manifested assent for NECC to act as their agent, and on their behalf, when [Defendants] contracted with NECC to procure compounded drugs from NECC to administer to their patients, including Mr. Hulsey. *See* Paragraphs 330 and 332 of the MC. Under Plaintiffs’ theory of agency, every hospital, health clinic and physician in the United States consents to every drug company to act as its agent by merely “procuring” drugs and medications from that drug company for their patients.

Florida law recognizes both an actual and an apparent agency relationship. “Essential to the existence of an actual agency relationship is (1) acknowledgment by the principal that the agent will act for him, (2) the agent's acceptance of the undertaking, and (3) control by the principal over the actions of the agent.” *Pycsa Panama, S.A. v. Tensar Earth Technologies, Inc.*, 625 F. Supp. 2d 1198, 1252 (S.D. Fla. 2008) *aff'd*, 329 F. App'x 257 (11th Cir. 2009) (*citing Villazon v. Prudential Health Care Plan*, 843 So. 2d 842, 853 (Fla. 2003) (*citing* Restat.2d of Agency, § 1 (1957))). Florida courts apply “a three-prong test under general agency law in order to determine the existence of apparent agency: first, whether there was a representation by the principal; second, whether a third



party relied on that representation; and, finally, whether the third party changed position in reliance upon the representation and suffered detriment.” *Id.* (citing *Almerico v. RLI Ins. Co.*, 716 So.2d 774, 777 (Fla.1998)).

While the existence of an agency relationship is generally a fact question, when a party bearing the burden of proving agency fails to produce evidence in support of its allegations or *where the evidence presented is so unequivocal that reasonable persons could reach but one conclusion*, a court may determine the lack of agency as a matter of law. *Pardo v. Tanning Research Labs., Inc.*, 996 F. Supp. 1222, 1225-26 (M.D. Fla. 1998) *aff’d sub nom. Pardo v. Tanning Research Labs.*, 170 F.3d 187 (11th Cir. 1999) (emphasis added) (citations omitted). Under Florida law, actual agency occurs when the principal specifically authorizes its agent to take certain actions. *Id.*

Defendants and NECC do not have an agency relationship; rather, Defendants merely purchased goods, or MPA, from NECC. Defendants prepared a “Prescription Order Form” to communicate to NECC the amount of MPA Defendants desired to purchase and, when NECC shipped MPA to Defendants, NECC provided an Invoice for the goods which Defendants paid. *See* Exemplar Prescription Order Form and Invoice attached as “Exhibit D.” Nothing in the Prescription Order Form or the Invoice acknowledges any type of an agency relationship. Further, nothing in the documents allows, or even suggests, that Defendants may control NECC’s action. The mere purchase of goods, as alleged in the Plaintiffs’ complaint, fails as a matter of law to establish any actual relationship between the Defendants and NECC. The instant Count must be dismissed.

Under the doctrine of apparent authority, agency will arise when the principal causes or allows others to believe that the individual has authority to conduct the act in question on the principal's behalf. *Id.* at 1226. The focus is on the appearance created by the principal, and not the appearance created by the agent. *Id.*

There is no evidence to support Plaintiffs' apparent agency claims against the Defendants. The evidence cited by Plaintiffs, when viewed in its best light with all inferences in Plaintiffs' favor, establishes only that Defendants procured compounded drugs from NECC. It does not constitute proof that Defendants even gave the impression that anyone from NECC was authorized to act on Defendants' behalf.

The instant count must be dismissed because there is no evidence to support Plaintiffs' claims of an agency relationship. The evidence in the instant case, or lack thereof, is similar to *Pardo*, where the evidence presented is so unequivocal that reasonable persons could reach but one conclusion, and that conclusion is there is no actual or apparent agency relationship. Simply put, a pain clinic merely purchasing goods, MPA in this case, from an unaffiliated third-party out of state company, without more, does not create an agency relationship.

**F. Plaintiffs' Claims Under Count XI, Civil Conspiracy (Against All Clinic Related Defendants) Must Be Dismissed Because the Factual Allegations Against Defendants, Do Not Raise a Right to Relief Above a Speculative Level**

Under Count XI, Plaintiffs allege Civil Conspiracy against the Defendants. Plaintiffs claim Defendants acted in concert with NECC, its agents and employees, to accomplish the unlawful purpose of circumventing Massachusetts Board of Pharmacy patient safety requirements. *See* Paragraph 338 of the MC. Plaintiffs argue that the conspiracy was committed when NECC requested patient lists, and Defendants "could

not provide such patient lists and NECC requested the [Defendants] submit any list of names to be provided to the Board.” *See* Paragraph 340 of the MC. Plaintiffs claim the Defendants “knew or should have known the patient names were required by virtue of the fact that NECC’s standard order form for MPA and other drugs requested patient specific information.” *See* Paragraph 341 of the MC. Plaintiffs appear to argue that by either failing to submit patient names to NECC or submitting patient names “regardless of whether those patients actually were or would be prescribed MPA or other NECC drugs” constitutes a criminal conspiracy. *See* Paragraph 340 of the MC. Plaintiffs further allege Defendants were aware of NECC’s intent to use such patient lists in order to subvert Massachusetts Board of Pharmacy requirements. *See* Paragraph 342 of the MC.

“While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, ... a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *United Technologies Corp. v. Mazer*, 556 F.3d 1260, 1269-70 (11th Cir. 2009) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1964–65, 167 L.Ed.2d 929 (2007) (citations omitted)). “Furthermore, the plaintiff’s factual allegations, when assumed to be true, ‘must be enough to raise a right to relief above the speculative level.’” *Id.* (same).

In order to state a claim for civil conspiracy, Plaintiffs must allege: “(a) an agreement between two or more parties, (b) to do an unlawful act or to do a lawful act by unlawful means, (c) the doing of some overt act in pursuance of the conspiracy, and (d) damage to plaintiff as a result of the acts done under the conspiracy.” *United*

*Technologies Corp. v. Mazer*, 556 F.3d 1260, 1271 (11th Cir. 2009) (citing *Charles v. Fla. Foreclosure Placement Ctr., LLC*, 988 So. 2d 1157, 1159–60 (Fla. 3d DCA 2008)).

In the instant case the Plaintiffs’ factual allegations, when assumed to be true, are not enough to raise a right to relief above the speculative level and should be dismissed. Regarding Plaintiffs’ allegations there was an agreement between Defendants and NECC to do an unlawful act or to do a lawful act by unlawful means, the only agreements alleged in the SFC and MC was that Defendants purchased medication from NECC and then submitted, or failed to submit, the proper patient lists. The MC makes a blanket assumption that Defendants failed to send a patient list or sent a “false” patient list. There is no evidence within the SFC or MC to support either allegation, other than mere speculations.

Further, Defendants do not practice medicine or pharmacy in the state of Massachusetts and therefore the Massachusetts Board of Pharmacy has no regulatory power over Defendants. Due to Defendants’ position in relation to the Massachusetts Board of Pharmacy, it is mere speculation that Defendants “knew or reasonably knew” the rules and regulations of the Board, and that it intended to defraud or subvert the Massachusetts Board of Pharmacy. Because Plaintiffs’ allegations are not enough to raise a right to relief above the speculative level, *United Technologies Corp.* supports the position that this Count must be dismissed.

**G. Plaintiffs’ Claims Under Count XII, Wrongful Death (Against Each Defendant), Must be Dismissed Because Plaintiffs Failed to Comply With Florida’s Medical Malpractice Statutory Pre-Suit Requirements**

Plaintiffs’ Count XII, Wrongful Death claim against Defendants, must be dismissed because Plaintiffs failed to comply with Florida’s Medical Malpractice

Statutory Pre-Suit Requirements. Plaintiffs allege that the Florida Wrongful Death Act, *Fla. Stat.* § 768.16 (2012) governs Plaintiffs' claims. Plaintiffs allege Defendants administered Mr. Hulsey an NECC compounded drug, which caused his death. The Wrongful Death Act states: "[w]hen the death of a person is caused by the wrongful act, negligence, default, or breach of contract or warranty of any person, including those occurring on navigable waters, and the event would have entitled the person injured to maintain an action and recover damages if death had not ensued, the person or watercraft that would have been liable in damages if death had not ensued shall be liable for damages as specified in this act notwithstanding the death of the person injured, although death was caused under circumstances constituting a felony." *Fla. Stat.* § 768.19 (2012).

Plaintiffs' Count XII, Wrongful Death claim against Defendants, must be dismissed because Plaintiffs failed to comply with Florida's Medical Malpractice Statutory Pre-Suit Requirements. "Florida law requires that before filing any claim for personal injury **or wrongful death** arising from medical malpractice, the claimant conduct an investigation of the claim and send the defendant(s) a notice of intent to sue, along with a corroborating opinion by a medical expert. *Fla. Stat.* § 766.203(2) (2005)." *Johnson v. McNeil*, 278 F. App'x 866, 871 (11th Cir. 2008) (emphasis added). Analysis in Section B. *supra* is as equally applicable to a Wrongful Death Claim allegedly caused by medical malpractice, as a general or gross negligence claim allegedly caused by medical malpractice. For the reasons cited within this section, as well as discussed under Section B., Plaintiffs' Wrongful Death Claim under Count XII must be dismissed.

**H. Plaintiffs' Claims Under Count XIII, Loss of Consortium (Against All Defendants), Must be Dismissed Because All Actionable Tort Claims Against Defendants Will Likely Be Dismissed and a Loss of Consortium Claim is Dependent upon the Existence of an Actionable Tort**

Loss of consortium is a derivative claim which is dependent upon the existence of an actionable tort causing harm to the spouse of the party claiming relief. *Vernon v. Med. Mgmt. Associates of Margate, Inc.*, 912 F. Supp. 1549, 1565 (S.D. Fla. 1996); see also *Gates v. Foley*, 247 So.2d 40, 45 (Fla.1971); *Perdomo v. Jackson Memorial Hospital*, 443 So.2d 298, 300 (Fla. 3d DCA 1983). In *Vernon*, the Court dismissed all the tort claims against the husband, and ruled that since all underlying tort claims were dismissed, it followed that the wife's consortium claim against the alleged tortfeasor must also be dismissed. *Id.* The rationale was developed in *Gates v. Foley*, 247 So. 2d 40, 45 (Fla. 1971), where the Florida Supreme Court stated that "[t]he rule that we now recognize is that the wife of a husband injured as a proximate result of the negligence of another shall have a right of action against that same person for her loss of consortium. We further hold that her right of action is a derivative right and she may recover only if her husband has a cause of action against the same defendant."

To the extent that all counts against the Defendants are dismissed, it follows that the claim for Loss of Consortium under Count XIII must also be dismissed.

**I. Plaintiffs' Claims Under Count XIV, Punitive Damages (Against All Defendants), Must be Dismissed Because All Actionable Tort Claims Against Defendants Must Be and Will Be Dismissed and a Loss of Consortium Claim is Dependent upon the Existence of an Actionable Tort**

Plaintiffs assert a claim for punitive damages against the Defendants, alleging that Defendants "were aware of, but consciously disregarded, a substantial and unjustifiable

risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiffs therefore are entitled to an award of punitive damages against all Defendants.” *See* Paragraph 363 of the MC. Plaintiffs’ conclusory allegations are insufficient to entitle Plaintiffs to recover punitive damages and therefore this count must be dismissed. Further, as a matter of law, Plaintiffs are not entitled to punitive damages based upon the alleged actions or inactions of the Defendants.

Under Florida law, in any civil action, no claim for punitive damages is permitted unless there is a reasonable showing by evidence in the record or proffered by the claimant which would provide a reasonable basis for recovery of such damages. *Fla. Stat. § 768.72 (1999)*. The statute creates for defendants a substantive legal right not to be subject to a punitive damages claim and ensuing financial worth discovery until the trial court makes a determination that there is a reasonable evidentiary basis for recovery of punitive damages. *Cradle to Crayons Childcare Center, Inc. v. Ramos*, 999 So. 2d 1090 (Fla. Dist. Ct. App. 1st Dist. 2009); *Estate of Esterline v. Avante at Leesburg, Inc.*, 845 So. 2d 1028 (Fla. Dist. Ct. App. 5th Dist. 2003). Merely setting forth conclusory allegations in the complaint is insufficient to entitle a claimant to recover punitive damages. *Porter v. Ogden, Newell & Welch*, 241 F.3d 1334, 1341 (11th Cir. 2001); *see also T.W.M. v. American Medical Sys., Inc.*, 886 F.Supp. 842, 845 (N.D.Fla.1995); *Bankest Imports, Inc. v. ISCA Corp.*, 717 F.Supp. 1537, 1542–43 (S.D.Fla.1989). Instead, a plaintiff must plead specific acts committed by a defendant. *Porter*, 241 F.3d at 1341; *See also Bankest Imports*, 717 F.Supp. at 1542–43.

In *Neill v. Gulf Stream Coach, Inc.*, 966 F. Supp. 1149, 1156 (M.D. Fla. 1997) the Court dismissed the plaintiff's claim for punitive damages reasoning that plaintiff plead punitive damages in a cursory manner. The *Neil* Court reasoned that pleading only in a cursory manner did not constitute a proffer creating a reasonable basis for recovery of punitive damages. *See Id. at 1156; see also Globe Newspaper Co. v. King*, 658 So. 2d 518, 520 (Fla.1995) ("To allow punitive damages claims to proceed as before would render section 768.72 meaningless").

Plaintiffs' two sentence claim under Count XIV fails to comply with the requirements set out in *Fla. Stat. § 768.72 (1999)*, is conclusory and therefore, insufficient to entitle a Plaintiffs to recover punitive damages.

Additionally, Plaintiffs seem to allege that Defendants' administration of medicine to a patient in need of medicine rises to the level worthy of punitive damages. The Restatement (Second) of Torts § 908 (1979) states the following:

- (1) Punitive damages are damages, other than compensatory or nominal damages, awarded against a person to punish him for his outrageous conduct and to deter him and others like him from similar conduct in the future.
- (2) Punitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others. In assessing punitive damages, the trier of fact can properly consider the character of the defendant's act, the nature and extent of the harm to the plaintiff that the defendant caused or intended to cause and the wealth of the defendant.

Procedurally, Plaintiff had not complied with mandatory pleading requirements to be allowed to assert a claim for punitive damages; no motion has been filed, proffered evidence provided and the court has not considered whether Plaintiff made a reasonable showing to establish, if allowed to plead the claim, that Plaintiff will be able to prove at



trial, by clear and convincing evidence, the claim. Accordingly, Count XIV must be dismissed.

Further, as discussed above under Sections C and D, the allegations fails to rise to the level of conduct required in Florida to plead a claim for punitive damages. Missing from the MC is the fact that neither Marion nor Dr. Shetty was aware that the NECC medication that they purchased was contaminated. Even if we accept, for the purpose of this Motion, that the medication was in fact contaminated, the Plaintiffs' arguments must fail as there are no allegations to support actual knowledge of contamination. In fact, Defendants reasonably believed, based upon the Microbiology Reports attached hereto as Exhibit "A," that the MPA medication they received was sterile. Administering medication to Mr. Hulsey by injection, with Mr. Hulsey's consent, as was done in the instant matter, falls far short of "outrageous conduct," "evil motive" or "reckless indifference" to the rights of others. As a matter of law, Plaintiff's attempt to make a claim for punitive damages is procedurally defective and, further, Defendants' actions and alleged inactions do not, and will not, rise to the level necessary to justify punitive damages and the claim should be dismissed.

**J. To the Extent the Court Does Not Dismiss All of the Counts Alleged against Defendants and Moved to Dismiss Under Sections A Through I, Defendants Assert in the Alternative That Those Counts Must Be Dismissed Because Plaintiffs Failed to Comply With Florida's Medical Malpractice Statutory Pre-Suit Requirements**

Assuming *arguendo* that Counts III; IV; VII; VIII; X; XI; XII; XIII; and XIV are not dismissed, either with or without prejudice, under the merits asserted under sections A through I, Defendants assert in the alternative that these Counts must be dismissed because Plaintiffs failed to comply with Florida's Medical Malpractice Statutory Pre-Suit

Requirements. “Florida law requires that before filing any claim for personal injury or wrongful death arising from medical malpractice, the claimant conduct an investigation of the claim and send the defendant(s) a notice of intent to sue, along with a corroborating opinion by a medical expert. Fla. Stat. § 766.203(2) (2005).” *Johnson v. McNeil*, 278 F. App'x 866, 871 (11th Cir. 2008). Analysis in Section B. *supra* is as equally applicable to all claims asserted against Defendants as all claims arise from medical care provided to Plaintiffs. For the reasons cited within this section, as well as discussed under Section B., these Counts must be dismissed.

WHEREFORE, the Defendants, Marion Pain Management Center, Inc., and Mangala J. Shetty, M.D., respectfully request that this Court **ALLOW** their Motion to Dismiss pursuant to Fed.R.Civ.P. 12(b)(6) and Local Rule 7.1.

Respectfully Submitted,  
The Defendants,  
MARION PAIN MANAGEMENT  
CENTER, INC. and  
MANGALA J. SHETTY, M.D.  
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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on this 12th day of March, 2014, a copy of the foregoing document was filed electronically with the United States District Court for the District of Massachusetts, which will send notification of such filing to all counsel of record, including below counsel:

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